IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JOSEPH HERBERT
40279 Wolfe Drive
Mechanicsville, MD 20659

Plaintiff,

v.

DEPUY SYNTHES SALES, INC.
d/b/a DEPUY SYNTHESE JOINT RECONSTRUCTION
325 Paramount Drive
Raynham, MA 02767
SERVE: **THE CORPORATION TRUST, INCORPORATED**
2405 York Road, Suite 201
Lutherville Timonium, MD 21093

and

DEPUY SYNTHES PRODUCTS, INC.
1101 Synthes Avenue
Monument, CO 80132
SERVE: **THE CORPORATION TRUST, INCORPORATED**
2405 York Road, Suite 201
Lutherville Timonium, MD 21093

and

MEDICAL DEVICE BUSINESS SERVICES, INC.
700 Orthopaedics Drive
Warsaw, IN 46581
SERVE: **THE CORPORATION TRUST, INCORPORATED**
2405 York Road, Suite 201
Lutherville Timonium, MD 21093

Defendants.

Case No.: _____

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COMPLAINT

COMES NOW, the Plaintiff, Joseph Herbert, by and through counsel, John P. Valente, III, and The Valente Law Group, who files this Complaint against Defendants, DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction; DePuy Synthes Products, Inc.; Medical Device Business Services, Inc.; (hereinafter collectively "Defendants") and, for the reasons therefore, states as follows:

PARTIES

1. That at all times relevant to this Complaint, Joseph Herbert (hereinafter "Plaintiff"), has been and continues to be a resident of and domiciled in St. Mary's County, Maryland.

2. That Defendant, DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction, is a Massachusetts corporation with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767. At all relevant times, this Defendant regularly conducted business in Maryland.

3. That Defendant, DePuy Synthes Products, Inc., is a Delaware corporation with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767. At all relevant times, this Defendant regularly conducted business in Maryland.

4. That Defendant, Medical Device Business Services, Inc., is an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582. At all relevant times, this Defendant conducted business in Maryland.

5. That at all times relevant, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

6. That each Defendant was involved, either directly or as described in paragraph five (5), in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DePuy AttuneTM Knee System (hereinafter "ATTUNE system"), as well as monitoring and reporting adverse events.

JURISDICTION AND VENUE

7. That this Court has original jurisdiction of this claim, in that the subject incident occurred within the boundaries of Charles County, Maryland.

8. That this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and diversity of citizenship exists between the parties.

9. That venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)2, because a substantial part of the events giving rise to Plaintiff's claims occurred in Charles County, Maryland, and Defendants conducted regular business in Maryland.

BACKGROUND

10. That total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

11. That in a TKA surgery, physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue

and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

HISTORY OF DEPUY KNEES AND THE ATTUNE SYSTEM

12. That according to Defendants, the ATTUNE system "builds on the LCS Complete Knee System and the Sigma Rotating Platform Knee," both of which are also Defendants' products.

13. That in or about 1977, Defendants introduced the LCS Complete Knee System which, at that time, included three options: a bicruciate-retaining option, a posterior cruciate-retaining option, and a cruciate sacrificing option (the rotating-platform design).

14. That Defendants introduced the P.F.C. Total Knee System in or about 1984. According to Defendants, clinical studies have proven the success of the P.F.C. design, with 92.6% survivorship at 15 years.

15. That based on this clinical success, according to Defendants, the company introduced the DePuy Synthes P.F.C. SIGMA System ("SIGMA system") in or about 1996.

16. That the SIGMA system was one of the most widely used TKAs worldwide, and Defendants quickly became one of the largest manufacturers of knee replacement devices in the United States. According to Defendants, the SIGMA system demonstrated excellent survivorship with 99.6% at 7 years.

17. That notwithstanding Defendants' alleged success with the SIGMA system, as reported by DePuy, the company began to tinker with the SIGMA system design in an effort to replicate the total flexion of the natural knee and maintain a competitive position in the market. This new project—one that Defendants boasted as their largest research and development project ever— carrying a price tag of approximately $200 million—resulted in the ATTUNE system.

A. 510(k) Approval of the Attune System and Regulatory History

18. That according to Defendants, the new ATTUNE system was an attempt to improve functional outcomes, provide more stability and simplify implantation of the contemporary total knee system.

19. That the resulting ATTUNE system purported to feature a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam, a tibial base which can be downsized or upsized two sizes versus the insert, novel patella tracking, lighter innovative instruments, and a new polyethylene formulation. Defendants sought FDA clearance for the new ATTUNE system through the "510(k)" process.

20. That Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be "substantially equivalent" to a product that has previously received FDA approval. The process requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance of introduction to the market. This is known as Premarket Notification – also called PMN or 510(k). This approval process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

21. That in or about 2010, Defendants were ready to take the ATTUNE system to market. In December 2010, Defendants received FDA clearance of the ATTUNE System under the "510k" notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee System. Consequently, Defendants received FDA 510(k) approval of the components of the ATTUNE system in 2010 and 2011 with only very limited, if any, testing of the new ATTUNE system.

22. That the ATTUNE system includes the Attune Tibial Base (510K Number K101433), also called the tibial tray, which, as compared to the SIGMA system, included a design

change to the keel, the surface texture and/or finish of the tibial baseplate and "combined with new technology to treat the underside of the implant," among other changes.

23. That the design and composition of the ATTUNE system, especially the tibial baseplate, was defective and failed at all times relevant herein, which resulted in harm to Plaintiff.

B. Launch of the DePuy Attune Knee System

24. That in or about March of 2013, Defendants introduced its ATTUNE system, including procedures for implantation, to surgeons and consumers. On March 20, 2013, Defendants issued a press release widely introducing its "latest innovation in total knee replacement—the ATTUNE Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

25. That according to the Press release, the ATTUNE system was "designed to provide better range of motion and address the unstable feeling some patients experience during everyday activities, such as stair descent and bending." According to Defendants, its "proprietary technologies include: … SOFCAMTM Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

26. That Defendants' launch strategy began with branding multiple "new" technologies and touting the project as one of the largest research and development projects in the history of the DePuy Synthes Companies, costing approximately $200 million. Defendants claimed the following features of the ATTUNE system: "the largest clinical program at DePuy," "improves value of TKA," "compares favorably in joint registries," and "significantly less symptomatic crepitus, primarily Sigma PS."

27. That the most notable improvement Defendants purported to make between the SIGMA and ATTUNE system is the patented S-curve design of the femoral component. This

feature, according to Defendants, conferred greater mid flexion stability as the implanted knee moves from extension to flexion because of the more gradual change in the femoral component radius of curvature. This design feature was also proposed to offer greater functional benefits and a greater range of movement as compared to other implants.

28. That however, the ATTUNE system did not deliver on these promises, resulting in significantly higher failure rates than previous knee counterparts of Defendants due to the debonding of the tibial baseplate. As a result, many knee replacement patients implanted with ATTUNE systems have had more expensive, more dangerous and less effective total knee replacement surgeries, and many have required or will require expensive and dangerous knee revision surgery to remove and replace the defective ATTUNE system.

29. That since the initial launch, Defendants have aggressively marketed the ATTUNE system.

FAILURES OF THE ATTUNE SYSTEM

30. That the primary reason the ATTUNE system fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the implant cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening has occurred at an unprecedented rate in patients implanted with an ATTUNE system.

31. That in many instances, loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. In fact, subsequent to the subject TKA involving Plaintiff, radiographic imaging demonstrated loosening of the tibial component.

32. That a loose artificial knee generally causes pain and, among other things, severely restricts a patient's daily activities as it can involve a severe physical and emotional burden for the patient, as was the case with Plaintiff after receiving the Attune system.

33. That once the pain becomes unbearable or the individual loses function of the knee, another operation, often called a "revision surgery," may be required to remove the knee implant and replace it with a new one, which Plaintiff underwent on March 5, 2019 for these reasons.

34. That the success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

35. That beginning in or about 2013 and 2014, Defendants became aware of safety issues with the ATTUNE system. These concerns were evidenced through failure reports submitted to and kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which houses medical device reports submitted to the FDA by reporters such as manufacturers, importers and device user facilities. Most related reports concern failures caused by ATTUNE system design elements which caused loosening and/or debonding at the tibial baseplate cement/implant interface. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE system resulting in subsequent revision surgeries.

36. That noticing the alarming rate of failure and subsequent revisions related to the ATTUNE system, in or about March of 2016, Defendants submitted a Section 510(k) premarket notice of intent to market the ATTUNE Revised system, which included a new stem, with added length and a keel for additional stability and recessed cement pockets intended to promote cement fixation. The stem of the ATTUNE Revised system was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

37. That on or about March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the first ATTUNE Revision Knee System ("ATTUNE Revised system"), which included the Attune Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

38. That without notifying consumers, doctors or patients, including Plaintiff and his physicians, Defendants attempted to replace the original Attune Fixed Base tibial baseplate with a new tibial baseplate, also called a tibial tray, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate is an admission, or at the very least strong evidence, that the original Attune tibial baseplate is defective and prone to failure. However, Defendants did not recall the defective tibial baseplate or inform consumers and surgeons about the dangers of its use.

39. That Defendants requested FDA approval of the new tibial baseplate by application dated March 17, 2017, which was "prepared" by Defendants in or about March of 2016. The application requested clearance of a new tibial baseplate component as part of the Attune system, which, upon information and belief, has been called the "Attune S+ Technology" ("ATTUNE S+") by Defendants. In particular, the application identified the design changes that were implemented with the ATTUNE S+, including a newly designed "keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or microblast finish.

40. That the "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following:

> The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance

fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond.

41. That Defendants knew about the design defects and resulting failures with the original ATTUNE tibial baseplate long before the newly designed tibial baseplate (ATTUNE S+) was cleared in or about June 2017, yet they failed to share this information with orthopedic surgeons using the ATTUNE systems. In fact, the application for approval for the ATTUNE S+ was submitted by Defendants to the FDA in or about March of 2016 and, upon information and belief, many surgeons were still in the dark about the new and improved ATTUNE system design at the time of Plaintiff's total knee replacement surgery on August 28, 2017.

42. That by March of 2016, Defendants had recognized the existence of high failure rates of the original ATTUNE tibial baseplate (which failed following Plaintiff's initial TKA), identified the defects and/or mechanisms of failure associated with it, researched and designed the new tibial tray/baseplate (ATTUNE S+), conducted testing of this new tibial baseplate, as detailed in the application, and submitted the application to the FDA.

43. That although Defendants knew about the high number of ATTUNE system failures resulting in revision surgeries, Defendants failed to warn surgeons, consumers and patients, and allowed the original, defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Plaintiff and his physician.

44. That in fact, beginning in or about December 2016, Defendants began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE systems were failing. Although Defendants decided to make a change, it did not inform the surgeons, consumers and/or patients. In responding to the MAUDE reports involving failures of ATTUNE tibial baseplates, Defendants frequently provided the following "Manufacturer Narrative":

The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance or other events within the quality system. (b)(4) has been undertaken to investigate further. ***The analysis and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4).*** DePuy considers the investigation closed at this time. Should the additional information be received, the information will be reviewed and the investigation will be reopened as necessary.

DEFENDANTS' MARKETING OF ATTUNE SYSTEMS

46. That according to Defendants, the ATTUNE system produces better stability of the knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative flexibility and efficiency, and implant longevity. Defendants aggressively marketed the ATTUNE system based on these assertions. Despite these claims, large numbers of revision cases appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.

47. That Defendants promised patients they could recover faster, and engage in more active lifestyles. Contrary to Defendants' representations, however, the ATTUNE system is prone to failure, causing patients to experience additional pain and injury.

48. That Defendants designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the sale and distribution of medical devices, and by these activities, caused the ATTUNE systems to be placed into the stream of commerce throughout the United States, including Maryland.

49. That Defendants actively and aggressively marketed to doctors and the public that the ATTUNE systems were safe and effective total knee prostheses.

50. That from the time that Defendants first began selling the ATTUNE systems, the product labeling and product information for the ATTUNE system failed to contain adequate information, instructions, and warnings concerning the increased risk that the ATTUNE system fails at an extremely high rate.

51. That upon information and belief, Defendants downplayed the health risks associated with the ATTUNE system through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Plaintiff's surgeon, and potential users of the ATTUNE system by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE system.

52. That based on the design changes made to the original Attune tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their premarketing and post-marketing analysis, knew or should have known that the ATTUNE system was prone to fail. Plaintiff alleges that the ATTUNE system is defective and unreasonably dangerous.

CASE SPECIFIC FACTUAL ALLEGATIONS

53. That on or about August 28, 2017, Plaintiff underwent a right-sided total knee replacement surgery at the University of Maryland Charles Regional Medical Center in La Plata, Charles County, Maryland. Plaintiff was implanted with the ATTUNE system, including, but not limited to, a fixed tibial insert and a fixed tibial baseplate, which was designed, manufactured, marketed, distributed, labeled, marketed and sold throughout the United States by Defendants. The ATTUNE system was purchased by Plaintiff.

54. That within one year after the ATTUNE system was implanted, Plaintiff began experiencing severe and persistent pain, discomfort, instability and difficulty ambulating caused by loosening of the components of the ATTUNE system in his right knee.

55. That in or about August of 2018, Plaintiff's physician, Gregg Ferrero, M.D., took and viewed radiographs which he indicated were suggestive of implant loosening.

56. That on or about March 5, 2019, Plaintiff underwent revision surgery due to loosening of the components of the ATTUNE system implanted in his right knee. This surgery was performed by Dr. Peter Trent at the University of Maryland Charles Regional Medical Center in La Plata, Maryland, during which Dr. Trent confirmed the tibial baseplate "was loose and came out easily by hand."

57. That neither Plaintiff nor his physicians were aware, by warning or otherwise, of the defects in the ATTUNE system, and would not have used the ATTUNE system had they been aware of the defective nature of the device.

58. That as a direct and proximate result of Defendants placing the ATTUNE system in the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative, monitoring, and pharmaceutical expenses, economic damages, severe and permanent injuries, and other related damages.

59. That all of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction, and unreasonably dangerous character of the ATTUNE system that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the ATTUNE system, Plaintiff would not have consented to the ATTUNE system being used in his total knee arthroplasty.

COUNT I
Negligence

60. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

61. That Defendants, individually and/or by and through their agents, servants, and/or employees, owed a duty to Plaintiff to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the ATTUNE device.

62. That Defendants, individually and/or by and through their agents, servants, and/or employees, failed to exercise ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the ATTUNE system into interstate commerce in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, including the loosening and/or debonding at the tibial plate, thereby breaching their duty to consumers, including Plaintiff.

63. That Defendants, individually and/or by and through their agents, servants, and/or employees, further owed Plaintiff the duty to:

(a) Design the ATTUNE system in a manner which was safe for those individuals who had the device surgically implanted;

(b) Design, manufacture, produce, create and/or promote the ATTUNE system after thoroughly testing it;

(c) Adequately and correctly warn Plaintiff and his physicians, hospitals, and/or healthcare providers of the dangers of the ATTUNE system;

(d) Recall their dangerous and defective ATTUNE system at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Ensure that the ATTUNE system was safe for its intended purpose; and

(f) Manufacture the ATTUNE system in a manner which was safe to those individuals who had it implanted.

64. That the Defendants, individually and/or by and through their agents, servants, and/or employees, breached their duties owed to Plaintiff, including, but not limited to, the following acts and/or omissions:

(a) Negligently designing the ATTUNE system in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the ATTUNE system without adequately, sufficiently, or thoroughly testing it;

(c) Failing to adequately and correctly warn Plaintiff and his physicians, hospitals, and/or healthcare providers of the dangers of the ATTUNE system;

(d) Failing to recall their dangerous and defective ATTUNE system at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Advertising and/or marketing the use of the ATTUNE system despite the fact that Defendants knew or should have known of its defects;

(f) Representing that the ATTUNE system was safe for its intended purpose when, in fact, it was unsafe;

(g) Manufacturing the ATTUNE system in a manner which was dangerous to those individuals who had it implanted; and

(h) Under-reporting, underestimating, and/or downplaying the serious danger of the ATTUNE system.

65. That Defendants knew or should have known that consumers, including Plaintiff, would suffer foreseeable injuries as a result of Defendants' failure to exercise ordinary care as described above. Moreover, Defendants knew or should have known that the subject ATTUNE system would be utilized in surgeries such as Plaintiff's procedure, and that the subject ATTUNE

system had a propensity to fail and/or malfunction and/or debond and/or loosen based on numerous adverse events reported in the Manufacturer and User Facility Device Experience database that chronicles failures and/or malfunctions and/or debonding and/or loosening identical to that which occurred subsequent to Plaintiff's surgery.

66. That all material times, Defendants knew of the defective nature of the ATTUNE system as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

67. That the failure of the subject ATTUNE system is a result that does not ordinarily occur absent negligent design and/or manufacture by Defendants, who, at all times, maintained exclusive control over the subject ATTUNE system before it was placed within its packaging.

68. That as a direct and proximate result of Defendants' negligence described above, the ATTUNE system failed and loosened, requiring Plaintiff to undergo a subsequent revision surgery and further additional medical care, as well as the economic and noneconomic damages described below.

69. That as a direct and proximate result of the negligent acts of Defendants, individually and/or by and through their actual and/or apparent agents, servants and/or employees, Plaintiff received severe and permanent injuries, all of which have caused him and will continue to cause him in the future great pain, suffering, mental anguish and other non-economic damages.

70. That as a further direct and proximate result of the negligent acts of Defendants, individually and/or by and through their actual and/or apparent agents, servants and/or employees, Plaintiff has been forced to expend and will continue to expend in the future, large sums of money

for hospitalizations, surgery, diagnostic studies, doctors, nurses, medical treatment, and pain medications for the treatment of the above-state injuries sustained by Plaintiff in this incident.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

COUNT II
Breach of Warranty of Merchantability

71. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

72. That Defendants, as designers, fabricators, manufacturers, marketers, sellers and/or suppliers of the subject ATTUNE system warranted that such artificial knee equipment was merchantable.

73. That the subject ATTUNE system was not merchantable and was instead defective as described above. Specifically, these defects in the ATTUNE system were the failure to design, manufacture, fabricate, and/or supply the tibial insert and tibial baseplate so as to prevent failure of the ATTUNE system, as well as loosening and/or debonding at the tibial baseplate and/or cement/implant interface.

74. That as a direct and proximate result of the breach of Defendants' warranty of merchantability, Plaintiff has sustained all the injuries and damages alleged above.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

COUNT III
Breach of Warranty of Fitness for a Particular Purpose

75. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

76. That Defendants, as designers, fabricators, manufacturers, marketers, sellers and/or suppliers of the subject ATTUNE system warranted that such knee system was fit for the purpose of providing a safe and effective TKA, free from any design, manufacturing, and/or latent defects.

77. That the ATTUNE system was not fit for the intended purpose of the TKA procedure performed on Plaintiff on or about August 28, 2017, due to Defendants' failure to design, manufacture, fabricate, and/or supply the tibial insert and tibial baseplate so as to prevent failure of the ATTUNE system, as well as loosening and/or debonding at the tibial baseplate and/or cement/implant interface. Consequently, Plaintiff's ATTUNE system failed and necessitated a revision surgery and the economic and noneconomic damages described herein.

78. That as a direct and proximate result of the unfitness of the subject ATTUNE system implanted into Plaintiff, Plaintiff has sustained all the injuries and damages alleged herein.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

COUNT IV
Strict Liability - Defective Design

79. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

80. That at all times herein mentioned, Defendants were the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributers of the ATTUNE system, which was defective and unreasonably dangerous.

81. That at all times relevant herein, the ATTUNE system was defective in its design or formulation in that it was not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The ATTUNE system was defective in design in that it lacked efficacy, had a high failure rate, posed a greater likelihood of injury, and was more dangerous than other available devices indicated for the same conditions and uses. Moreover, the ATTUNE system was defective, because the design of the tibial insert and tibial baseplate failed to ensure that the subject product did not fail by the loosening and/or debonding at the tibial baseplate and/or cement/implant interface. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the ATTUNE system did not outweigh its risks.

82. That the defective condition of the ATTUNE system rendered it unreasonably dangerous and/or not reasonably safe, and the ATTUNE system was in this defective condition at the time it left the hands of Defendants. The ATTUNE system was expected to and did reach Plaintiff and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

83. That Plaintiff was unaware of the significant hazards and defects in the ATTUNE system. The ATTUNE system was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Plaintiff used the ATTUNE system, it was being utilized in a manner that

was intended by Defendants. At the time Plaintiff had the ATTUNE system implanted, it was represented to be safe and free from latent defects.

84. That Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

85. That Defendants are liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the ATTUNE system, which was unreasonably dangerous for its reasonably foreseeable use because of its design defects.

86. That Defendants knew or should have known of the danger associated with the use of the ATTUNE system, as well as the defective nature of the ATTUNE system, but continued to design, manufacture, sell distribute, market, promote, and/or supply the ATTUNE system so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the ATTUNE system.

87. That as a direct and proximate result of the defective designs and use of the implantation of the subject ATTUNE system, Plaintiff has sustained all the injuries and damages alleged herein.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

COUNT V
Strict Liability - Defective Manufacture

88. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

89. That at all times material hereto, Defendants manufactured, designed, tested, marketed, distributed, sold, and/or supplied the ATTUNE system and placed it in the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to result in early loosening and/or debonding at the tibial baseplate and/or cement/implant interface and failure of the device. The subject product was unreasonably dangerous in construction or composition.

90. That alternatively, the ATTUNE system purchased and implanted in Plaintiff was defective because it varied from Defendants' intended design and contained unreasonably dangerous conditions.

91. That as a direct and proximate result of Defendants placing the defective ATTUNE system into the stream of commerce, with the manufacturing defect described above, Plaintiff sustained all the injuries and damages alleged herein.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

COUNT VI
Strict Liability - Failure to Warn

92. That Plaintiff hereby adopts and incorporates all allegations and averments above as if set forth fully herein at length.

93. That at all times material hereto, Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the ATTUNE system into the stream of commerce knowing the devices would then be implanted in patients in need of a knee prosthesis, including Plaintiff. In the course of the same, Defendants

directly advertised and/or marketed the product to health care professionals and consumers, including Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the ATTUNE system. Defendants breached this duty.

94. That the ATTUNE system was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the ATTUNE system and the comparative severity and duration of such adverse side effects.

95. That the warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, and/or severity of potential side effects, specifically the risk of early debonding and/or loosening of the tibial baseplate and/or cement/implant interface.

96. That Defendants failed to perform adequate testing which would have demonstrated that the ATTUNE system had potentially serious side effects about which Defendants should have provided full and proper warnings.

97. That the ATTUNE system was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

98. That had Defendants reasonably and properly provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Plaintiff's physicians, would have used the ATTUNE device, and no consumer, including Plaintiff, would have purchased and/or used the ATTUNE device.

99. That Defendants, as designers, fabricators, manufacturers, marketers, sellers and/or suppliers of the subject ATTUNE system, owed a duty of care to Plaintiff and/or his treatment

providers, including but not limited to Dr. Ferrero and University of Maryland Charles Regional Medical Center, to advise as to the defective design and/or manufacture of the subject ATTUNE system and/or advise the doctors performing the surgical procedure on Plaintiff as to the possibility and/or probability of a future malfunction of the ATTUNE system, including, but not limited to, the debonding and/or loosening of the tibial baseplate and/or cement/implant interface.

100. That Defendants breached their duty of care to Plaintiff and/or his treatment providers, including but not limited to Dr. Ferrero and University of Maryland Charles Regional Medical Center, in failing to advise as to the defective design and/or manufacture of the subject ATTUNE system and/or advise the doctors performing the surgical procedure on Plaintiff as to the possibility and/or probability of a future malfunction of the ATTUNE system, including, but not limited to, the debonding and/or loosening of the tibial baseplate and/or cement/implant interface.

101. That as a direct and proximate result of the failure to warn Plaintiff as described above, Plaintiff has sustained all the injuries and damages alleged above.

WHEREFORE, Plaintiff, Joseph Herbert, demands judgment against the Defendants, and each of them, individually, and jointly and severally, for compensatory damages in the amount of Two Million Dollars and no cents ($2,000,000.00), plus a separate award for costs and attorney's fees, and such other relief as this Honorable Court deems just and proper.

Respectfully submitted,

THE VALENTE LAW GROUP

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PRAYER FOR JURY TRIAL

The Plaintiff, Joseph Herbert, prays for a trial by jury in the above-captioned case.

John P. Valente, III